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Dockets Management Branch (HFA-305)
Docket No. 98-N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

I oppose the Draft M.O.U. being proposed by the FDA. In particular, I object to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Originally I made the decision to take HRT in order to protect myself from heart attacks and osteoporosis. Initially, 10/94, I was placed on Premarin and Progesterone. In order to alleviate symptoms (breakthrough bleeding) my dosage was increased. Six to seven months later I learned I was overdosed on Estrogen. I then learned about the specialized compounding pharmacies and have been using Estradiol Gel and Progesterone Cream ever since. I can even adjust it myself therefore just using enough to alleviate my symptoms. I could never acquire finite amounts using Premarin and Progesterone tablets.

I also in 11/94, I developed what I now know as small fiber peripheral neuropathy. No tests have revealed why I developed this, but I do not need additional symptoms of menopause. It is difficult to sleep with peripheral neuropathy and hot flashes and night sweats made sleep near impossible. With the help of the compound Estradiol and Progesterone I no longer have those problems. If you took this away from we women who depend on this it would be a catastrophe for us.

As my life experience tells me, more than likely this is a ploy from the large pharmaceutical companies who are not selling as much Premarin, etc. as a result of women becoming smarter and learning what compounding pharmacies have to offer. I know that local pharmacies will never do compounding....that's what they used to do and prescriptions were more individualized, but in the days of hurry, hurry and money, money all they do now is count pills or measure liquids that are shipped compounded.

Sincerely,

Deborah Clifton
Deborah Clifton

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A circular postmark from Grand-Auvergne, dated 28 MAY 1939. The text "GRAND-AUVERGNE" is curved along the top, "28 MAY" is in the center, and "1939" is at the bottom.

Abstract